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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,562	01/26/2001	William J. Curatolo	PC9674AJTJ	8513
28523	7590	05/02/2008		
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			EXAMINER FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	
			NOTIFICATION DATE	DELIVERY MODE
			05/02/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

<b>Office Action Summary</b>	<b>Application No.</b> 09/770,562	<b>Applicant(s)</b> CURATOLO ET AL.	
	<b>Examiner</b> BLESSING M. FUBARA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,15,17,22,23,26,28-38,49-51 and 53-56 is/are pending in the application.
- 4a) Of the above claim(s) 28-35 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,15,17,22,23,26,36,37,49-51 and 53-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/9/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The examiner acknowledges receipt of request for extension of time filed 01/31/08, IDS filed 04/09/08; response to election requirement filed 1/31/08; request for continued examination under 37 CFR 1.114 and request for extension of time and amendment and remarks, all filed 6/21/07. Claims 1 and 15 are amended. Claims 1, 4, 15, 17, 22, 23, 26, 28-38, 49-51 and 53-56 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/07 has been entered.

#### ***Election/Restrictions***

2. Applicant's election of ziprasidone and claims 1, 4, 15, 17, 22, 23, 26, 36, 37, 49-51 and 53-56 in the reply filed on 6/21/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 28-35 and 38 are withdrawn from consideration.

#### ***Response to Arguments***

3. **Previous rejections that are not reiterated herein are withdrawn.**

4. The declaration filed on 6/21/07 under 37 CFR 1.131 is sufficient to overcome the Kigoshi et al., US 6,254,889 reference.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 15, 17, 22, 23, 26, 36, 37, 49-51 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obara et al. ("Influence of processing variables on the properties of free films prepared from aqueous polymeric dispersions by a spray technique," in International Journal of Pharmaceutics 126 (1995) 1-10) in view of Akiyama et al. (US 5,576,025).

Obara discloses that pharmaceutical dosage forms spray dried dispersions using hydroxypropylmethyl cellulose acetate succinate (AQOAT = HPMCAS) produced particles with a mean particle size of 5  $\mu\text{m}$  (abstract, para. 1). Obara does not mention any specific drugs. But poorly water soluble antipsychotic drugs are known to be formulated into coated granules by spray coating with polymers such as HPMCAS (column 6, lines 14 and 26; column 9, line 13; column 11, line 60; column 12, line 52; column 13, lines 39-44).

Claim 1(a) and (b) are the properties of the dosage form. Claim 1 recites spray dried dispersion which in claim 4 is amorphous when undispersed and the recitation in claim 4 is also directed to the properties of the dosage form. Claim 15 is also met because the AUC is a property of the dosage form because the spray dried dosage form would be capable of showing the AUC. The particles sizes of 5 or 10  $\mu\text{m}$  is less than 100  $\mu\text{m}$  such that particle size in claims

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23 and 26 is rendered obvious by the prior art except there is a factual evidence that the less than 100  $\mu\text{m}$  provides unexpected result while also noting that any particle size that is less than 100  $\mu\text{m}$  would meet the limitation of less than 100  $\mu\text{m}$ . The dosage form of the prior art is capable of exhibiting the concentration parameters recited in claim 22 since the composition of the prior art and the claims contain HPMC and an active agent that is poorly soluble. Regarding claim 50, the prior art does not say that the product is free of any solvent. Because both the drugs of the prior art and the claimed invention are poorly water soluble, and the drugs such as chlorpromazine disclosed in the prior art meets the requirements of claim 36, then the solubility parameter recited in claim 53 would be inherent to the dose of the prior art. Regarding claim 37, since the prior art spray coats antipsychotic drug with HPMCAS, it would be reasonably expected that another antipsychotic drug such as claimed in claim 37 would also be successfully coated. However, the prior art does not teach the ratio of the drug to polymer. But, taking the generic teachings of the prior art, one having ordinary skill in the art at the time the invention was made would have good reason to use specific amounts drug and polymer in a defined drug/polymer ration that would lead to the anticipated success of spray coated/dried dosage forms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/  
Examiner, Art Unit 1618